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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,852	09/22/2000	Per Johan Lundberg	1103326-0686	1116

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,852

Applicant(s)

LUNDBERG ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-20 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-20 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makino et al. (EP 0237200-A2).

The claimed invention refers to an oral pharmaceutical dosage form of omeprazole comprising a core coated with a membrane, process of making and method of administering said dosage form.

Makino et al. discloses pharmaceutical compositions of benzimidazole derivatives, including omeprazole, said compositions prepared by mixing the drug with basic inorganic salts and additives, including vehicles such as sucrose and cellulose, binders such as hydroxypropylcellulose and PVP, and lubricants, such as talc (See e.g., p. 8, lines 14-23).

Makino et al. teaches that the mixture can be made up into dosage forms, such as tablets and capsules and the tablets may be coated by known methods to mask the taste or to provide enteric or sustained release properties, and includes ethylcellulose among the coating agents used in the invention (See e.g., p. 8, lines 34-41). In Example 8, Makino et al. teaches that the powder used to coat the spherical granules contains sucrose and corn starch, which are modifying agents (See e.g., p. 14).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Makino et al. to device sustained release dosage forms of omeprazole. Because of the teachings of Makino et al., that sustained release pharmaceutical compositions of omeprazole exhibit excellent gastric anti-secretory and anti-ulcer activities, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

3. Claims 1, 3-20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanai et al. in view of Bergstrand et al.

Yanai et al. provides pharmaceutical compositions for oral administration comprising a fumagillol derivative in admixture with a gastric acid secretion-inhibitor, including a proton pump inhibitor, such as omeprazole (See e.g., col. 14, lines 1-17). Yanai et al. teaches that the coated drug-containing cores of the invention may be in the form of tablets and pills and the core can be prepared by an ordinary production method, by mixing the drug with appropriate excipient, binder, disintegrant and lubricant (See e.g., col. 14, lines 30-38). Yanai et al. includes sugars, cellulose and calcium phosphate among the excipients, PVP and low-substituted hydroxypropylcellulose among the disintegrants and talc among the lubricants used in the invention (See e.g., col. 14, lines 39-49). Yanai et al. teaches that the core may be surface coated with a protecting agent, such as hydroxyalkylcellulose (See e.g., col. 14, line 66 to col. 15, line 9).

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Thus, Yanai et al. provides oral dosage forms comprising omeprazole and the additives claimed in the instant application, without an enteric coating. Yanai et al. is deficient in not including a modifying agent in the coating.

Bergstrand et al. provides multiple unit tableted dosage forms of omeprazole, said dosage forms comprising a core material comprising seeds layered with a mixture of the active substance with binders, fillers, disintegrating agents, alkaline additives or other pharmaceutical ingredients, and a separating layer applied to the core by coating and comprising polymers, such as ethylcellulose, and additives, such as anti-tacking agents, including talc, and silicate (See e.g., col. 3, line 64 to col. 6, line 44).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions disclosed by Yanai et al., by including an anti-tacking agent in the membrane layer, to strengthen the diffusion barrier, as taught by Bergstrand et al.. Because of the teachings of Bergstrand et al., that talc increases the thickness of the membrane and improve the stability of the active substance, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Claims 1, 3-20 and 23-26 are rejected.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

March 6, 2002


THURMAN K. PAGE
SUPERVISORY/PATENT EXAMINER
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